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Foclivia (*pandemic influenza vaccine* [*H5N1*] [*surface antigen, inactivated, adjuvanted*])

An overview of Foclivia and why it is authorised in the EU

What is Foclivia and what is it used for?

Foclivia is a vaccine used in adults to protect against flu when a 'pandemic' has been officially declared by the World Health Organization (WHO) or the European Union (EU). A flu pandemic occurs when a new type (strain) of flu virus can spread easily from person to person because people have no immunity (protection) against it. A pandemic can affect most countries and regions around the world. Foclivia would be given according to official recommendations.

Foclivia contains some parts of inactivated (killed) influenza (flu) virus. It contains a flu strain called A/Vietnam/1194/2004 (H5N1).

How is Foclivia used?

Foclivia is given by injection into the upper arm muscle or the thigh in two doses, at least 3 weeks apart.

The vaccine can only be obtained with a prescription and should be used according to official recommendations.

How does Foclivia work?

Foclivia is a 'pandemic preparedness' vaccine. This is a special type of vaccine that can be developed to help with the management of a future pandemic.

Before a pandemic starts, nobody knows which strain of flu virus will be involved, so companies cannot prepare the correct vaccine in advance. Instead, they can prepare a vaccine that contains a strain of flu virus specifically chosen because nobody has been exposed to it, and to which nobody is immune. They test this vaccine to see how people react to it, allowing them to predict how people will react when the flu strain causing a pandemic is included in the vaccine.

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Vaccines work by preparing the immune system (the body's natural defences) to defend itself against a disease. Foclivia contains some parts the H5N1 virus.The virus has been first inactivated so that it does not cause disease. During a pandemic, the virus strain in Foclivia will have to be replaced by the strain causing the pandemic before the vaccine can be used.

When a person is given the vaccine, the immune system recognises the virus as 'foreign' and makes antibodies against it. When the person comes into contact with this or a similar virus, these antibodies, together with other components of the immune system, will be able to kill the viruses and help protect against the disease.

The immune system will then be able to produce antibodies more quickly when it comes into contact with the virus again. This helps to protect against the disease caused by the virus. The vaccine also contains an 'adjuvant' to increase the vaccine's effectiveness.

What benefits of Foclivia have been shown in studies?

The main study of Foclivia included 486 healthy people (a third of whom were over the age of 60) and compared the ability of two doses of Foclivia to trigger the production of antibodies (immunogenicity). The participants received two injections of Foclivia, containing either 7.5 or 15 micrograms of haemagglutinin (a protein found in flu viruses), 21 days apart. The main measures of effectiveness were the levels of antibodies against the flu virus in the blood before vaccination, on the day of the second injection (day 22), and 21 days later (day 43).

According to EMA's criteria, a pandemic preparedness vaccine needs to bring about protective levels of antibodies in at least 70% of people for it to be considered suitable.

The study showed that Foclivia produced an antibody response that satisfies these criteria. Twenty-one days after the second injection, 86% of the people receiving the vaccine with 7.5 micrograms haemagglutinin had levels of antibodies that would protect them against H5N1. The figure was 85% in people who received the 15-microgram dose.

What are the risks associated with Foclivia?

The most common side effects with Foclivia (which may affect up to 1 people in 10) are headache, sweating, arthralgia (joint pain), myalgia (muscle pain), reactions at the site of the injection (redness, swelling, hardening, bruising, pain), fever, feeling unwell, tiredness and shivering. The majority of these side effects disappear within 1 to 2 days. For the full list of all side effects of Foclivia, see the package leaflet.

Foclivia should not be given to people who have had an anaphylactic reaction (severe allergic reaction) to any of the components of the vaccine, or to any substances found at trace levels in the vaccine, such as egg, chicken protein, kanamycin or neomycin (antibiotics), formaldehyde and cetyltrimethylammonium bromide (CTAB). However, if a pandemic has started, it may be appropriate to give the vaccine to these people, as long as facilities for resuscitation are available.

Why is Foclivia authorised in the EU?

The European Medicines Agency decided that Foclivia's benefits are greater than its risk and it can be authorised for use in the EU.

Foclivia has been authorised under 'exceptional circumstances'. This means that, because the vaccine is a pandemic preparedness vaccine and does not yet contain the strain of flu virus that is causing a

pandemic, it has not been possible to obtain full information about the final pandemic vaccine. Every year, the European Medicines Agency will review any new information that may become available and this summary will be updated as necessary.

What information is still awaited for Foclivia?

Since Foclivia has been authorised under exceptional circumstances, the company that markets Foclivia will collect information on the safety and effectiveness of the final pandemic vaccine when it includes the flu strain responsible for a pandemic in the vaccine.

What measures are being taken to ensure the safe and effective use of Foclivia?

Recommendations and precautions to be followed by healthcare professionals and their patients for the safe and effective use of Foclivia have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Foclivia are continuously monitored. Side effects reported with Foclivia are carefully evaluated and any necessary action taken to protect people who receive Foclivia.

Other information about Foclivia

Foclivia received a marketing authorisation valid throughout the EU on 19 October 2009. The authorisation was based on the authorisation granted to Focetria in 2007 ('informed consent').

Further information can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/foclivia.

This overview was last updated in 09-2019.